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(54) Title: METHOD AND KIT FOR THE CHARACTERIZATION OF ANTIBIOTIC-RESISTANCE MUTATIONS IN *MYCOBACTERIUM TUBERCULOSIS*

(57) Abstract

Amplification and cycle sequencing primer sets have been developed for the detection and analysis of antibiotic resistance-associated mutations in defined regions of the *rpoB* (rifampin), *katG* (isoniazid), *oxyR-ahpC* PR (isoniazid), *mabA* (isoniazid), *rpsL/s12* (streptomycin), *16S/rrs* (streptomycin), *embB* (ethambutol), *pncA* (pyrazinamide), *gyrA* (ciprofloxacin) and *23S* (azithromycin) genes of *Mycobacterium tuberculosis*. These primers can be used in a method for detection and characterization of *Mycobacterium tuberculosis* present in a sample. The method includes the steps of obtaining a sputum sample suspected of containing *M. tuberculosis*, performing a first sequencing procedure, with or without prior amplification, on the sample to detect the presence of *M. tuberculosis*, and if present to evaluate the *rpoB*, *katG*, *rpsL/s12* and *23S* genes for the presence of antibiotic-resistance inducing mutations; and (c) if *M. tuberculosis* is detected in step (b), performing a second sequencing procedure, with or without prior amplification, on the sample to evaluate the additional genes for the presence of antibiotic-resistance inducing mutations.

